 <b>BIOSENSORS INTERNATIONAL</b>	<b>PREMARKET NOTIFICATION</b>	<b>DISPOSABLE PRESSURE MONITORING SYSTEM</b>	
	<b>SPECIAL 510K</b>	Page	1 of 3

**SECTION 5 510K SUMMARY** *[As required by section 807.92(c)]*

APR 19 2007

Prepared on 19 December 2006

**1. Applicant Information**

Company Address: Biosensors USA  
20280 Acacia Street, Suite 300  
Newport Beach, CA 92660, USA

Establishment Number: 2084493

Contact Person: Sara Toyloy  
Phone: (949) 553 8300  
Facsimile: (949) 553 9129

**2. Device Identification**

Common Name: Disposable Pressure Monitoring System

Trade Name: Accutrans Disposable Pressure Monitoring System

Classification Name: Transducer, Blood-Pressure, Extravascular

**3. Predicate Devices**


1. BIOTRANS™ PRESSURE MONITORING KIT (K981747)
2. UTAH DISPOSABLE PRESSURE TRANSDUCER (K841788)

**4. Device Description**

Biosensors's Accutrans Disposable Pressure Transducer System consists of a pressure monitoring kit with pressure tubing connected to the single-use disposable transducer with an integrated pressure sensor. The transducer can come with or without an integral flush device. The complete configuration can be pole-mounted or patient mounted and is provided sterile and non-pyrogenic.

**5. Intended Use**

Accutrans Disposable Pressure Transducer Kit is intended to convert the hemodynamic waveform from the patient's catheter, through the disposable pressure transducer with integrated pressure sensor, into electrical signals which can be displayed using separate monitoring equipment. Accutrans Disposable Pressure Transducer is provided with or without an integral 3cc/hr or 30cc/hr flush devices. Kits with 30cc/hr flush devices are designed exclusively for use with an infusion pump for neonatal and infant applications.

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The disposable pressure transducer, with the integrated pressure sensor, is intended for direct coupling to sterile catheters with fluid (saline) flows in contact with the patient bloodstream.

#### 6. Summary of Technological Characteristics of Device in relation to Predicate Devices(s)

Biosensors plans to introduce a fully disposable pressure monitoring kit, Accutrans models, in addition to the current Biotrans™ models already cleared by 510K (K981747). The materials used in Accutrans transducer are the same as Biotrans™ transducer, however the Accutrans transducer incorporates an in-built sensor. The technology of Accutrans pressure transducer is substantially equivalence to the Utah Deltrans™ pressure transducer, which is also cleared by 510K (K841788).

The subject Accutrans models have a similar intended use and design construction with equivalent components as the predicated Biotrans™ and Deltrans™ models. The safety and effectiveness of the subject device models have been assessed and discussed further in Section 7 below.

#### 7. Assessment of Performance Data used to Justify Substantial Equivalence

##### Test Summary, In-vitro


Functional performance tests were performed on the Accutrans transducer to evaluate the performance and the reliability of the transducer in accordance to recommended performance standards, IEC 60601-1-34 and ANSI/AAMI BP22-1994. Based on the test results which meet the acceptance criteria, the transducer is concluded to be safe and effective for its intended use.

##### Test Summary, Biocompatibility

Biocompatibility tests were performed in accordance to ISO10993-1 Part 1: *Evaluation & Testing* and USP 27 <88> *Biological Reactivity Tests, In Vivo*. Based on the test results, the Accutrans Pressure transducer is biocompatible and safe for its intended use.

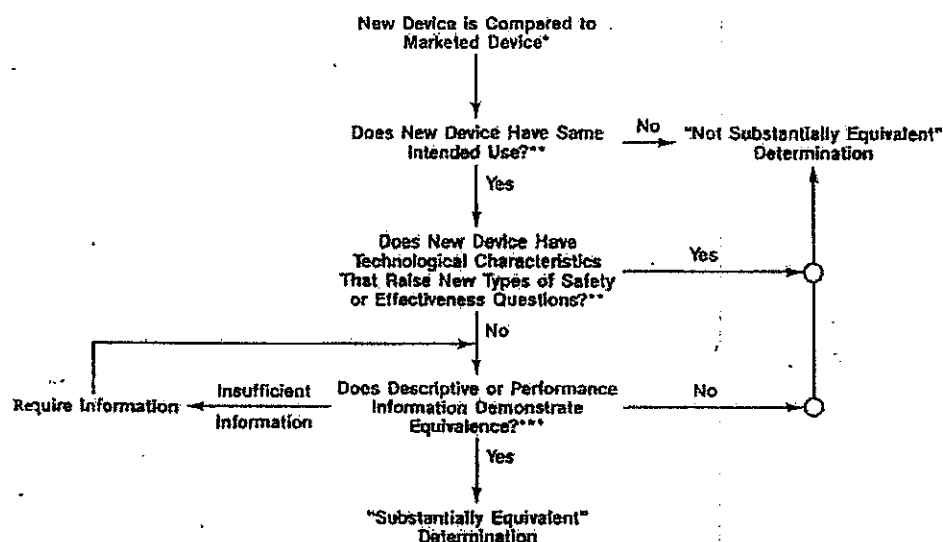
#### 8. Conclusion:

The Functional performance Tests and Biocompatibility tests have demonstrated that the Biosensors Accutrans Disposable Pressure Monitoring System is substantially equivalent to the predicate devices and is safe and effective for its intended use.

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## 510K Substantial Equivalence Decision-Making Tree

## ATTACHMENT I

510(k) "Substantial Equivalence"  
Decision-Making Process (Overview)

\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Device is Unclear.

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

\*\*\* Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Decision to substantial Equivalence is based on 510(k) Memorandum #K86-3, 510(k). Questions in the decision path are evaluated as follow:

**Q1. Does New Device have same intended use?**

Yes. The intended use of the new range of models of the Accutrans transducer is the same as the Biotrans transducer currently listed.

**Q2. Does New Device have Technological Characteristics that raise new types of Safety or effectiveness questions?**

No. The new models were designed to have a built-in sensor unlike the current models but the additional sensors housing material and gel were evaluated for biocompatibility and functional performance and demonstrated no new safety and effectiveness issue arises due to technological difference.

**Q3. Does descriptive or Performance information demonstrate equivalence?**

Yes. The product description and the intended use on the labeling and the instruction for Use enclosed in Appendix A between the subject models and predicated models demonstrate the substantial equivalence. The physical and performance characteristics evaluated in Table 1 in Section 5 - Description of the Modification to the device also showed substantial equivalence between the subject device and predicated device.

**Conclusion:**

As according to the decision path, the Accutrans Disposable Pressure Monitoring kit can be submitted using substantial Equivalence.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 19 2007

Biosensors International  
c/o Sara Toyloy  
20280 Acacia St. Suite 300  
Newport Beach, CA 92660

Re: K070710

Trade/Device Name: Accutrans Disposable Pressure Monitoring System  
Regulation Number: 21 CFR 870.2850  
Regulation Name: Extravascular blood pressure transducer  
Regulatory Class: Class II  
Product Code: DRS  
Dated: March 9, 2007  
Received: March 14, 2007

Dear Ms. Toyloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

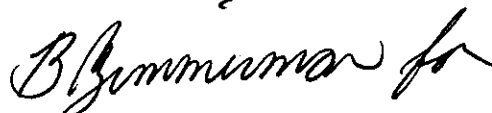
Page 2 – Ms. Toyloy

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.


If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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#### SECTION 4 INDICATIONS FOR USE

Common Name: DISPOSABLE PRESSURE MONITORING SYSTEM  
 Trade Name: ACCUTRANS PRESSURE MONITORING SYSTEM

##### 1. Intended Use / Indications for Use:

*Accutrans Disposable Pressure Transducer Kit* provides the fluid pathway components that are intended to convert the hemodynamic waveform from the patient's catheter, through the disposable pressure transducer with integrated pressure sensor, into electrical signals which can be displayed using separate monitoring equipment. The whole kit is fully disposable and consists of pressure monitoring lines and the Accutrans Disposable Pressure Transducer.

*Accutrans Disposable Pressure Transducer:* The disposable pressure transducer is provided with or without an integral 3cc/hr or 30cc/hr flush devices. Kits with 30cc/hr flush devices are designed exclusively for use with a infusion pump for neonatal and infant applications. The disposable pressure transducer, with the integrated pressure sensor, is intended for direct coupling to sterile catheters with fluid (saline) flows in contact with the patient bloodstream. *Accutrans Disposable Pressure Transducer Kits* are available for modular assembly of an IV pole-mount transducer organizer system, or for portable on-patient mounting.

*AccuTrans Pressure Monitoring Kits* and *AccuTrans Disposable Transducer* are indirectly in contact with the blood path and hence, are supplied sterile and is intended for single use only. Pole-mounts, backplates and transducer adapter cables are accessories that are to be used externally outside the human body, and hence supplied non-sterile but hygienically clean. Between surgical cases of patient, suitable cleaning instructions should be followed to minimize cross contamination between patient and health worker.

Prescription Use ☒

or

Over-the-Counter Use ☐

(Per 21CFR801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. J. Zimmerman  
 (Division Sign-Off)  
 Division of Cardiovascular Devices  
 510(k) Number K070710